510(k) Summary
Aleutian IBF System
K2M, Inc.

APR 0 3 2014

This safety and effectiveness summary for the Aleutian IBF System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175

Contact Person:
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K2M, Inc.
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Date Prepared: March 13, 2014

2. Tradename: Aleutian IBF System
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device with Bone Graft, lumbar (Product Code: MAX)
Intervertebral Fusion Device with Bone Graft, cervical (Product Code: ODP)
Spinal Vertebral Body Replacement Device (Product Code: MQP)
Regulation Number: 888.3080, 888.3060
Device Class: Class II

3. Description of the device:

The Aleutian Spinal System consists of a hollow tube or horseshoe-shaped structures. The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates.

Materials: The implants are manufactured from Medical Grade PEEK per ASTM F2026. Tantalum beads/ rods are to be made of Grade UNS R05200, UNS R05400 according to ASTM F560.

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the cervical and lumbar segments of the spine.

The purpose of this submission is to incorporate titanium implants into the system.

4. Intended Use:

When used as a cervical intervertebral body fusion device, the Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the Aleutian implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

When used as vertebral body replacement devices the Aleutian implants are indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aleutian implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

For all the above indications the Aleutian implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

5. Predicate or legally marketed devices which are substantially equivalent:

Documentation was provided which demonstrated that the subject Aleutian Spinal System components are substantially equivalent to devices previously cleared in K2M's Aleutian Spinal System (K082698, K101302, K103169, K110843, K113138, K130699).

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

Previously cleared Aleutian spacers were tested in static compression, static torsion and dynamic compression per ASTM F2077. An engineering rationale determined that the proposed spacers do not represent a new worst case for testing and are therefore considered substantially equivalent to the predicates referenced.

7. Conclusion:

There are no significant differences between the Aleutian Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive SE
Leesburg, Virginia 20175

Re: K133614
Trade/Device Name: Aleutian IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX, MQP
Dated: February 5, 2014
Received: February 6, 2014

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133614

Device Name
Aleutian IBF System

Indications for Use *(Describe)*

When used as a cervical intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

When used as vertebral body replacement devices the ALEUTIAN implants are indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The ALEUTIAN implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

For all the above indications the ALEUTIAN implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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